

## GUIDEWIRE FOR A FREE STANDING INTERVASCULAR DEVICE HAVING AN INTEGRAL STOP MECHANISM

5 *Sub* *C1* ~~This application is a continuation-in-part application of copending U.S. Serial  
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### Technical Field

10 The present invention relates generally to a guidewire for positioning and removing emboli capture and recovery devices (ECRD) such as small filters in a vein or artery, and more particularly to a guidewire with an integral stop mechanism which, when expanded or extended, permits the guide wire to move freely with respect to the filter while preventing the guidewire from being inadvertently removed from association with the filter and when collapsed or retracted permits the guidewire to be inserted through or removed from the filter.

### Background of the Invention

20 In recent years, a number of intervascular medical devices have been designed which are adapted for compression into a small size to facilitate introduction into a body vessel such as an arterial or vascular passageway and which are subsequently expandable into contact with walls of the passageway. These devices, among others, include stents, such as those shown by U.S. Patent No 5,540,712 and blood clot filters such as those shown by U.S. Patent No. 5,669,933 which expand and are held in position by engagement with the inner wall of a vessel. It has been found to be advantageous to form such devices of a thermal shape memory material having a first,

5 relatively pliable low temperature condition and a second, relatively rigid high-temperature condition. By forming such devices of temperature responsive material, the device in a flexible and reduced stress state may be compressed to fit within the bore of a delivery catheter when exposed to a temperature below a predetermined transition temperature, but at temperatures at or above the transition temperature, the device

10 expands and becomes relatively rigid.

10 Known self expanding medical devices have been formed of Nitinol, an alloy of titanium and nickel which provides the device with a thermal memory. The unique characteristic of this alloy is its thermally triggered shape memory, which allows a device constructed of the alloy to be cooled below a temperature transformation level to a martensitic state and thereby softened for loading into a catheter in a relatively compressed and elongated state, and to regain the memorized shape in an austenitic state when warmed to a selected temperature, above the temperature transformation level, such as human body temperature. The two interchangeable shapes are possible because of the two distinct microcrystalline structures that are interchangeable with a small variation in temperature. The temperature at which the device assumes its first configuration may be varied within wide limits by changing the composition of the alloy. Thus, while for human use the alloy may be focused on a transition temperature range close to 98.6°F, the alloy readily may be modified for use in animals with

15 different body temperatures.

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25 In recent years advances have been made in the treatment of blood vessel stenosis or occlusion by plaque, thrombi, embolic, or other deposits which adversely reduce or block the flow of blood through a vessel. Balloon angioplasty or similar transluminal treatments have become common for some blood vessel lesions, but for all such procedures, plaque and emboli dislodged during the procedure are free to flow within the lumen of the vessel and possibly cause substantial injury to a patient.

In an attempt to contain and remove emboli and other debris, balloon angioplasty coupled with irrigation and aspiration has been performed as illustrated by

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U.S. Patent No. 5,883,644 and International Publication No. WO 98/39046 to Zadno-Azizi et al. This procedure requires complete vessel occlusion cutting off all blood flow which imposes severe time constraints on the procedure. Additionally, the balloons involved in the procedure are affixed to elongate guidewires or small elongate catheters  
5 which extend for a substantial distance through blood vessels to the location of the stenosis or occlusion, and it is practically impossible to prevent some back and forth longitudinal motion of these elongate elements within a vessel during a procedure. This movement of the guidewire or catheter to which a balloon is attached causes the balloon to move back and forth and abrade emboli from the vessel wall downstream of the balloon containment area.  
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15 Angioplasty is often not a preferred treatment for lesions in the carotid artery because dislodged plaque can enter arterial vessels of the brain causing brain damage or even death. As indicated by U.S. Patent No. 5,879,367 to Kaganov et al., carotid endarterectomy is a surgical procedure used to remove a lesion in the carotid artery, but this procedure also involves substantial risk of dislodged embolic material.

20 In an attempt to contain dislodged emboli during a procedure to clear blood vessel stenosis or occlusion, a variety of distal filters have been devised such as those shown by U.S. Patent No. 5,814,064 and International Publication Nos. WO 98/38920 and WO 98/39053 to Daniel et al. as well as U.S. Patent Nos. 5,827,324 to Cassell et al., 5,846,260 to Maahs and 5,876,367 to Kaganov et al. These filters are secured to the distal portion of a guidewire or catheter and are deployed distally from the stenosis or occlusion to capture embolic material. Once the distal filter is positioned and expanded into contact with the wall of the blood vessel, an angioplasty balloon, a stent, or other devices are introduced over the proximal end of the guidewire or catheter to which the filter is attached and moved into position in the area of the occlusion or stenosis spaced proximally from the filter.  
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Known guidewire or catheter attached distal filters have been subject to a number of disadvantages. First, since the elongate catheter or guidewire to which the

filter is attached is used to guide over the wire devices during a subsequent procedure, it is extremely difficult if not impossible to prevent longitudinal movement of the wire or catheter after the filter has been deployed. This causes the filter to move back and forth within the vessel with resultant abrasion by the filter of the vessel wall, and such  
5 abrasion not only causes trauma to the vessel wall but also operates to dislodge debris which is free to flow distally of the filter. Thus filter movement after the filter is deployed somewhat defeats the purpose of the filter. Also, it is often desirable during a procedure to exchange guidewires, and such an exchange is not possible with an attached filter.

10 Additionally, the retrieval of known distal filters while retaining captured embolic material has proven to be problematic. Many cone shaped filters with wide, upstream proximal open ends tend to eject captured embolic material through the open end as the filter is collapsed. Also, many distal filters are formed by a mesh material which is expanded by a filter frame, and when the frame closes to collapse the filter for withdrawal through a catheter, the mesh folds creating outwardly projecting pleats. These pleats snag on the withdrawal of the catheter making retrieval of the filter 15 difficult and often causing the filter to spill captured embolic material.

Recently, it has become of concern that if the guidewire is made to be  
20 displaceable with respect to a filter or other intervascular device, there is the possibility that the device could become disassociated with the guidewire and consequently could migrate and become lost within the vessel. Accordingly, there is a need for a mechanism to provide selective association of the guidewire with a free standing, unsecured intervascular device when necessary while also being capable of stopping travel of the device away from the stenosis or occlusion in order to alleviate concerns  
25 regarding free migration of the device within a blood vessel.

Summary of the Invention

A primary object of the present invention is to provide a combination intervascular device and guidewire wherein the guidewire is longitudinally movable relative to the intervascular device.

It is an object of the present invention to provide a novel and improved 5 guidewire for confidently positioning a free standing filter for expansion within a blood vessel to capture dislodged embolic material.

Another object of the present invention is to provide a novel and improved 10 guidewire for confidently positioning a free standing filter for use during a procedure to treat blood vessel stenosis or occlusion which does not cause filter movement which results in trauma to the luminal wall during guidewire, balloon and stent exchanges and which can be associated with the filter in a manner to facilitate longitudinal movement of the guidewire relative to the filter while precluding filter migration.

A further object of the present invention is to provide a novel and improved 15 guidewire for positioning a free standing filter for use during a procedure to treat blood vessel stenosis or occlusion which is formed to facilitate intra-procedural guidewire exchanges and which reduces concern for the disassociation of the filter from the guidewire during normal procedures.

Yet another object of the present invention is to provide a novel and improved 20 guidewire for use with a free standing filter during a procedure to treat blood vessel stenosis or occlusion which is formed to remain stationary after expansion independent of guidewire or catheter motion which maintains an association with the filter to ensure proper removal of the filter upon completion of the procedure.

A still further object of the present invention is to provide a novel and improved 25 guidewire for association with the positioning of ECRD including a stop mechanism in the area of a distal end thereof to expand or extend and collapse or retract on actuation thereby forming a mechanical stop preventing the guidewire from being inadvertently removed from the ECRD.

These and other objects of the present invention are accomplished by providing an elongated guidewire having a stop mechanism thereon which is receivable in a receiving member extending centrally through an intervascular device provided with an open ended channel which may be configured to receive a plurality of different sized guidewires. The guidewire stop mechanism is positioned in the area of a distal end of the guidewire and may be selectively expanded or extended and collapsed or retracted to permit selective association with the intervascular device. When positioned through the receiving member of the intervascular device, the stop mechanism can be expanded or extended to prevent the loss of the device while still permitting the guidewire to move longitudinally with respect to the device. The stop mechanism may take on numerous configurations namely that of a balloon, a grappling hook, a buckled tube, a braided structure, barbs, biased bosses or any mechanism which is remotely expandable or extendable and collapsible or retractable from a guidewire. In the retracted position, the stop member should pass freely through the receiving member of the intervascular device, but in the expanded position, the stop member should be radially spaced from the inner wall of a blood vessel while precluding migration of the intervascular device over the distal end of the guidewire.

Brief Description of the Drawings

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Figure 1 is a view in side elevation of the free standing filter which can readily accommodate the guidewire of the present invention in the expanded configuration having the guidewire in accordance with the present invention positioned therein with the stop member expanded;

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Figure 2 is a partially sectional view in side elevation of a second free standing filter which can readily accommodate the guidewire of the present invention;

Figure 3 is a partially sectional view of the free standing filter of Figure 2 within a delivery tube having the guidewire in accordance with the present invention positioned therein with the stop member retracted;

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Figure 4 is an expanded sectional view of a distal end of a guidewire in accordance with the present invention including a stop mechanism in the form of a balloon therein in an expanded condition;

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Figure 5 is an expanded sectional view of a distal end of a guidewire in accordance with an alternative embodiment of the present invention including a stop mechanism in the form of a grapple hook in an extended position;

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Figure 6 is an expanded sectional view of a distal end of a guidewire in accordance with an alternative embodiment of the present invention including a stop mechanism in the form of a buckled tube in an expanded condition;

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Figure 7 is an expanded sectional view of a distal end of a guidewire in accordance with an alternative embodiment of the present invention including a stop mechanism in the form of barbs in an extended position;

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Figure 8 is an expanded view of a distal end of a guidewire in accordance with an alternative embodiment of the present invention including a stop mechanism in the form of a boss element in an extended position.

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#### Description of the Preferred Embodiments

Referring to Figure 1, a free standing filter 10 which is suitable for accommodating the guidewire 12 in accordance with the present invention is formed

5 around a central tube 11 defining an open ended channel which forms the longitudinal axis for the filter 10 and which slidingly receives the guidewire 12. The frame of the filter is formed by a stent 14 which may be collapsed inwardly toward the tube 11 and which expands outwardly away from the tube to the substantially cylindrical open ended configuration shown in the drawings. Ideally, this stent is formed of thermal shape 10 memory material and is of the type shown by U.S. Patent No. 5,540,712, although other expandable stents can be used. The stent 14 is coupled at one end to the central tube 11 by elongate lead wires 16 which extend between an open proximal end 18 of the stent and a spaced coupling 20 which is secured to the central tube 11. It should be readily appreciated by those skilled in the art that the guidewire 12 in accordance with present 15 invention may be used in conjunction with any ECRD, stent, or other intervascular medical device sized for positioning in a body vessel such as an arterial or vascular passageway without departing from the spirit and scope of the present invention.

10 In the example illustrated in Figure 1, extending around the stent 14 and attached thereto is a flexible, fine mesh filter material 22 which opens at the proximal end 18 of the stent and covers the body of the stent. Ideally, the stent extends over this mesh filter material. At the distal end 24 of the stent, the fine mesh filter material projects 15 outwardly to form a flexible conical section 26 with an apex 28 connected to a coupling 30 which slides on the tube 11 in spaced relation to the stent distal end 24. Thus when 20 the stent expands as shown in the drawings, the mesh filter material forms a substantially cylindrical section 32 which opens at the proximal end of the stent and a flexible, closed conical section 26 which extends beyond the distal end of the stent to catch and collect small particles. The fine filter mesh may be formed of suitable 25 biocompatible material such as polyester or a PTFE material and is coated with thromboresistant materials such as, for example, Phosphoral Choline or Hyaluronic Acid. The mesh is a braided material or elastomeric mesh which normally conforms to the exterior shape of the central tube 11, but which stretches to expand outwardly away from the tube when the stent 24 expands. Thus the mesh is biased toward the tube 11,

and when the stent collapses inwardly toward the tube, the mesh contracts back to the exterior shape of the tube and does not form pleats.

In the operation of the filter 10, the stent with the mesh filter material is inserted in a collapsed condition into a delivery tube 34 and guidewire 12 extends through the central tube 11. Then the delivery tube is used to deliver the filter 10 over the guidewire 12 to a desired position within a body vessel whereupon the filter is ejected from the delivery tube. Now the previously collapsed stent 14 expands into contact with the walls 36 of the vessel (shown in broken lines) thereby expanding the flexible mesh filter material which was previously collapsed within the delivery tube with the stent. The guidewire 12 may now be used to guide other devices into the vessel, and since the guidewire can move freely in a longitudinal direction within the tube 11, longitudinal movement of the guidewire will not result in movement of the expanded filter.

Once the stent 14 has expanded against the wall 36 of the vessel, the guidewire 12 can be removed and replaced with a new guidewire of a different size. The tube 11 is preferably formed with an internal dimension of sufficient size to accept .014 inch diameter to .035 inch diameter guidewires. It may often be desirable to initially use a very fine guidewire (.014") to cross a lesion and position the filter 10 and to then exchange this fine guidewire for a thicker wire. The details of the association of the guidewire with the tube 11 will be set forth in detail hereinbelow.

The fine mesh filter material 22, when expanded, should have a pore size within a range of 100 Mm to 150 Mm to capture and retain embolic material sized in excess of the pore size while permitting blood flow in the direction of the arrow 38 line in Figure 1 between the wires 16 and into the proximal end 18 of the stent 14. The blood and embolic material flows through the and into the flexible conical section 26 of the fine mesh filter material where the embolic material is trapped while the blood passes through the filter material.

To remove the filter 10 with the captured embolic material, the stent 14 is collapsed against the tube 11 for withdrawal through a catheter or delivery tube 34.

Preferably the stent is formed of the thermal shape memory material such as nitinol and may be collapsed by cooling the stent to a temperature below a transition temperature. It is important to note that the embolic material has been captured within the conical section 28, so that when the stent collapses against the tube 11, it positively closes the mouth of the conical section preventing material from escaping as the filter is drawn into the tube 34. The stent forces the entire longitudinal extent of the section 32 against the tube 11 to prevent the escape of material from the conical section 28.

10 The guidewire 12 has an elongate, flexible body 13 which extends from a distal end of the wire 15 to a proximal end 17 which projects beyond the proximal end of the catheter or delivery tube 34. Adjacent to the distal end 15 of the guidewire 12 is an expandable and contractable stop member 19 which moves between a contracted position adjacent to the guidewire and an expanded position as shown in Figure 1. In the contracted position of the stop member, the stop member is dimensioned to move freely with the guidewire 12 through the tube 11, but once through the tube, the stop member can be manually or automatically expanded to prevent migration of the filter over the distal end of the guidewire. In the expanded position, the stop member has an outer dimension which is larger than the internal dimension of the channel through the tube 11, but the outer dimension of the expanded stop member is radially spaced from the inner wall 36 of the blood vessel. This is important as contact by the stop member with the vessel wall would dislodge plaque downstream of the filter 10 as the guidewire moves during an intervascular procedure.

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25 With the stop member 19 in the expanded position, the guidewire 12 can still move longitudinally relative to the filter 10, but may not be withdrawn from the filter nor may the filter migrate over the distal end of the guidewire. A number of stop member structures will subsequently be discussed, but the stop member could be formed of two or more short arms 21 and 23 secured at one end to the guidewire 12. These

arms can be constructed of spring metal or of nitinol so that they lie flat against the guidewire as it passes through the catheter 34 and spring outwardly as the guidewire and filter leave the catheter.

5 Referring now to Figures 2 and 3, a second example of a free standing filter which may readily accommodate the guidewire 12 in accordance with the present invention is indicated generally at 40. For unimpeded passage through a catheter or delivery tube 34, it is beneficial to form a filter with a frame which completely surrounds and protects the filter mesh material. Thus the filter 40 includes a cellular frame 42 which is preferably formed of thermal shape memory material such as nitinol, and this frame when expanded includes a central section 44 having a substantially tubular configuration, a proximal end section 46 and a distal end section 48, both having a substantially conical configuration. A central tube 50, similar in size and structure to the tube 11, forms the central longitudinal axis for the filter 40 and extends through the filter and outwardly from the proximal and distal sections of the frame 42. The distal end of the tube 50 is provided with a tapered atraumatic molded tip 52 configured to center and guide the filter within the delivery tube 34.

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The central section 44 of the frame 42 includes a plurality of interconnected cells 54 which are substantially equal in size and which are defined by spaced sidewalls 56 and 58 which extend substantially parallel to the tube 50 and the longitudinal axis of the filter. Adjacent cells 54 in a row of cells extending around the central tube 50 are connected together by their adjacent sidewalls 56 and 58, and these sidewalls remain substantially parallel to the tube 50 in both the expanded and collapsed configuration of the filter 40 as illustrated in Figures 2 and 3. The opposite ends of each cell are formed by outwardly inclined endwall sections 60 and 62 which meet at an apex 64. Extending in a distal direction from the apex 64 of alternate cells 54 at the proximal end 20 25 of the central section 44 are short, straight stabilizers 66 which engage the vessel wall

36 when the filter is expanded and aid to preclude movement of the filter in a distal direction.

The proximal end section 46 and distal end section 48 of the frame 42 are formed of cells 68 with tapered sidewalls 70 and 72 which extend at an angle to the central tube 50 to form the tapered conical end sections of the frame. Proximal end section 46 of the frame is secured to the tube 50 by a coupling 74, and distal end section 48 is secured to a coupling 76 which slides on the tube 50. The couplings 74 and 76 are provided with radiopaque markers 78 and 80 respectively.

Fine mesh filter material 82 of the type previously described for the filter 10 is positioned within the central and distal sections of the frame 42. This filter material is bonded to at least the first row of cells 54 in the proximal end of the central section 44 of the frame, and at the distal end of the frame the filter material is secured to the tube 50 adjacent to the coupling 76 by a coupling 84. Thus the filter material forms a cone when the filter 40 is expanded, and the open proximal end of the cone is positively closed when the proximal end row of cells of the central section 44 collapse against the tube 50.

As shown in Figure 3, when the filter 40 moves along the guidewire 12 through the delivery tube 34, the mesh filter material 82 is enclosed within the frame 42 which protects the filter material. Also, when an expanded filter is contracted and drawn back into the delivery tube, the frame engages the delivery tube and precludes the filter from catching or snagging on the delivery tube.

With reference now to Figure 4, an initial embodiment of the guidewire set forth in accordance with the present invention is illustrated therein. Figure 4 illustrates a distal end of the guidewire 12 which includes the stop mechanism 100 in the form of an elastic balloon mounted around the guidewire which is expandable and collapsible with respect to the guidewire 12. The guidewire defines an enclosed, central chamber 102 which extends from the proximal end of the guidewire to the stop mechanism 100 and through which air can be provided to expand the balloon. The balloon 110 is

expandable and collapsible with respect to the guidewire 12 by way of ports 112 and 114 which connect the interior of the balloon to the channel 102. As can be appreciated by one of ordinary skill in the art, when the balloon 110 of the guidewire 12 is expanded to a condition illustrated in Figure 4, a filter or other free standing intervascular device, 5 if dislodged from a vessel during an angioplasty or other procedure, would be stopped by the stop mechanism 100 in that the balloon is expandable to a dimension greater than that of the tube 11 of the filter or device but to a dimension which is less than the fully expanded dimension of the intervascular device. Accordingly, the operation can confidently take place knowing that the filter or device will not become lost within the vessel. Further, in order to permit the exchange of guidewires as referred to hereinabove, the balloon is selectively collapsible so as to allow the guidewire 12 to be intentionally removed from the tube 11 in order to allow for exchange of guidewires.

10 With reference to Figures 5, 6, 7 and 8, various embodiments of the present invention are set forth. As noted from Figure 5, extendable and retractable grappling 15 hooks 116 are mounted to slide within the channel 102 and are provided to form a positive stop which is extendable from the guidewire 12 for a sufficient radius so as to ensure that the tube 11 of the filter cannot pass thereby. The grappling hooks 116 may be extendable from the guidewire 12 in any known manner. For example, a flexible rod 20 117 slidable within the channel 102 and connected to the hook extensions 118 can move axially with respect to the guidewire 12 and permit the extension and retraction of the grappling hooks 116.

25 The grappling hooks 116 may be extended and retracted through openings 104 formed on opposite sides of the guidewire which open into the channel 102. The grappling hooks may be formed of spring metal strips which curl outwardly when the hooks are extended or may be formed of strips of thermal shape memory material such as nitinol having a temperature transition level such that the hooks curl to the configuration shown in Figure 5 when they are extended from the guidewire within a blood vessel. Again, the extended configuration of the hooks is such that they cannot

pass through the tube 11, but when fully extended, they do not extend to the extent of the extended position of the intervascular device through which the guidewire passes.

Alternatively, as illustrated in Figure 6, the stop mechanism 100 may take the configuration of a buckle tube 119 which is slidably mounted on the guidewire 12 but is attached to the guidewire at its distal end 121. When the tube 119 is displaced relative to the guidewire toward the distal end 106 of the guidewire, the wall of the tube will buckle outwardly thus forming a circumferential extension 123. As with the grappling hooks 116, this circumferential extension extends radially for a distance greater than a diameter of the tube 11 but less than the expanded position of the filter or other intervascular device through which the guidewire passes. Accordingly, the filter would be prevented from traveling beyond the end of the guidewire 12 when the stop mechanism 100 is in the expanded condition. The buckle tube has a thin, flexible wall which reengages the guidewire when the buckle tube is moved axially toward the proximal end of the guidewire.

In accordance with yet another embodiment of the present invention, the stop mechanism 100 may take on the form of barbs 120 which are extendable and retractable with respect to the guidewire 12. Again a mechanism which is moved axially with respect to the guidewire 12 may be utilized in order to extend and retract the barbs 120 with respect to the guidewire 12. The barbs 120 when extended would be of a dimension greater than that of the tube 11 of the filter or intervascular device and when retracted would be permitted to readily pass through the tube 11.

The barbs 120 may be formed of spring metal with each having an end secured at 122 to the guidewire 12. These barbs, when retracted, lie within depressions 124 formed in the exterior surface of the guidewire, and when released, the spring bias of the barbs causes them to extend outwardly as shown in Figure 7. An elongate, flexible tether 126 is connected to the free end of each of the barbs 120 and passes through a hole 128 into the channel 102 in the guidewire 12. When the tethers 126 are drawn

toward the proximal end of the guidewire, the barbs 120 are retracted into the depressions 124.

In Figure 8, the stop mechanism 100 takes the form of double boss elements 130 which are spring biased with respect to the guidewire 12 and pressed outwardly by an 5 elongate cam actuator 132 which extends axially through the channel 102 in the guidewire 12. The actuator 132 includes a chamfered cam surface 134 which cooperates with the boss elements 130 to extend such elements outwardly with respect to the guidewire 12. Again the outward extension of the boss elements would be of a dimension greater than that of the tube 11 of the filter thus preventing passage of the 10 filter beyond the end of the guidewire 12 when the boss elements are extended.

Each boss element extends through an opening 136 in the guidewire and is attached to a mounting arm 138 secured within the channel 102. The mounting arms 138 spring bias the bosses 130 into the channel 120, but when the actuator 132 is moved toward the distal end 106 of the guidewire, the cam surface 134 forces the bosses 15 outwardly against the spring bias through the openings 136.